ARTICLE 61-05

RADIOPHARMACEUTICAL SERVICES

CHAPTER 61-05-01
RADIOPHARMACEUTICAL SERVICES

61-05-01-01. Purpose and scope. It is unlawful to receive, possess, or transfer radioactive drugs, except in accordance with North Dakota Century Code chapter 43-15. It is also unlawful for any person to provide radiopharmaceutical services unless that person is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with North Dakota Century Code chapter 43-15 and state board of pharmacy regulations and regulations of the North Dakota department of health, with the exception of a medical practitioner for administration to the practitioner's patients. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions of any radioactive material license required by the North Dakota department of health pursuant to North Dakota Century Code chapters 23-20 and 23-20.1. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of regulations of the state board of pharmacy and the North Dakota department of health.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-02. Definitions.

1. "Authentication of product history" includes identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

2. "Internal test assessment" includes conducting those tests of a quality assurance necessary to ensure the integrity of the test.

3. "Radiopharmaceutical quality assurance" includes the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

4. "Radiopharmaceutical service" includes the compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of radiopharmaceuticals.

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61-05-01-03. General requirements for pharmacies providing radiopharmaceutical services.

1. A pharmacy providing radiopharmaceutical services shall only be managed by a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of the nuclear pharmacist. The nuclear pharmacist is responsible for all operations of the licensed area and shall be in personal attendance at all times that the pharmacy is open for business. In emergency situations, in the pharmacist's absence, the pharmacist may designate one or more other qualified licensed professionals to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

2. Pharmacies providing radiopharmaceuticals shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handlingradiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least twenty-five square feet [2.32 square meters] of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office area. A pharmacy handling radioactive drugs

exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy before approval of the license.

3. Pharmacies providing radiopharmaceutical services shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.

4. Pharmacies providing radiopharmaceutical services shall maintain records of acquisition and disposition of all radioactive drugs.

5. Pharmacies providing radiopharmaceutical services shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

6. Radioactive drugs are to be dispensed only upon a prescription from a medical practitioner authorized to possess, use, and administer radiopharmaceuticals. A pharmacist providing radiopharmaceutical services may transfer to authorized persons radioactive materials not intended for drug use, in accordance with North Dakota rules and regulations pertaining to radiation control.

7. A prescription for a radiopharmaceutical shall be for an individual patient. A pharmacy may furnish radiopharmaceuticals for office use only to medical practitioners authorized to possess, use, and administer radiopharmaceuticals for an individual patient.

8. In addition to any labeling requirements of the state board of pharmacy for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with: (a) the standard radiation symbol; (b) the words "Caution–Radioactive Material"; (c) the radionuclide; (d) the chemical form; (e) the amount of radioactive material contained, in millicuries or microcuries; (f) if a liquid, the volume in cubic centimeters; (g) the requested calibration time for the amount of radioactivity contained.

9. The immediate container shall be labeled with: (a) the standard radiation symbol; (b) the words "Caution–Radioactive Material"; (c) the name, address, and telephone number of the pharmacy; and (d) the prescription number.

10. The amount of radioactivity shall be determined by radiometric methods for each individual dose immediately prior to dispensing.

11. Pharmacies may redistribute national drug administration approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

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61-05-01-04. General requirements for pharmacists to manage a pharmacy providing radiopharmaceutical services. A qualified nuclear pharmacist shall:

1. Meet minimal standards of training for medical uses of radioactive material.

2. Be a currently licensed pharmacist in this state.

3. Have received a minimum of ninety contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy.

4. Attain a minimum of one hundred sixty hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program in an accredited college of pharmacy.

5. Submit an affidavit of experience and training to the state board of pharmacy.

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61-05-01-05. Library. Each pharmacy providing radiopharmaceutical services shall have current editions or revisions of:

1. United States Pharmacopoeia, with supplements.

2. National Formulary, with supplements.

3. State laws and regulations relating to pharmacy.

4. State and federal regulations governing the use of applicable radioactive materials.

5. United States public health service, Radiological Health Handbook.

6. Nuclear Medicine–by Blahd.

7. Medical Radiation Physical–by Hendree.

8. Medical Radiation Biology–by Pizzarello and Wetcofske.

9. P.D.R. for Radiology and Nuclear Medicine.

10. Principles of Radiosotope Methodology–by Chase and Rabinwotz.

11. Current issues of Journal of Nuclear Medicine.

The board of pharmacy recognizes that the library needed will depend on the type of radiopharmaceutical services offered. Variations in the required library may be granted by the board of pharmacy.

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61-05-01-06. Minimum equipment requirements. Each pharmacy providing radiopharmaceutical services shall have the following equipment:

1. Radiation laboratory monitor (a stationary one away from activity).

2. Gamma counter.

3. Portable ionization chamber (to determine contamination and other physic procedures).

4. Sufficient quantity of lead bricks, leaded glass of high density, and leaded syringe shields.

5. Refrigerator with freezer.

6. Class A prescription balance or balance of greater sensitivity.

7. Single channel scintillation counter.

8. Pyrogen oven.

9. Portable radiation survey meter capable of detecting 0.005 microcuries of the radionuclides in question.

10. Chromatographic equipment.

11. Fumer hood.

12. Chemical exhaust hood.

13. Electronic balance.

14. Lighted microscope.

15. Auto clave–for steam sterilization.

16. Dry heat oven (for heat sterilization and to dry glassware).

17. Hotplate.

18. Lead shielded water bath.

19. Glassware.

20. Other equipment necessary for radiopharmaceutical services provided as required by the board of pharmacy.

The board of pharmacy recognizes that the equipment needed will depend on the type of radiopharmaceutical services offered. Variations for required equipment may be granted by the board of pharmacy.

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